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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/851,965	05/06/1997	ANDREW A. YOUNG	224/042	6500

7590 12/12/2001

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EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1627	27

DATE MAILED: 12/12/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application No. 08/851,965	Applicant(s) Young et al.
	Examiner Bennett Celsa	Art Unit 1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 12, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 4-10, 13-16, and 19-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *1, 2, 4-7, 9, 10, 13-16, and 19-29* is/are allowed.

6) ☒ Claim(s) *8, 30, and 31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Response to Amendment

Applicant's amendment dated 3/12/01 in paper no. 26 is hereby acknowledged.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 1-2, 4-10 and 13-16 and 19-31 are currently pending and under consideration.

Claims 1-2, 4-7, 9, 10, 13-16, 19-29 are allowable over the prior art of record.

Claims 8, 30 and 31 stand rejected.

Withdrawn Objection(s) and/or Rejection(s)

Applicant's amendment has overcome the rejection of claims 14, 18 and 19 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kolterman et al. WO 95/07098 (3/95) alone and further in view of the specification to demonstrate inherency. E.g. See MPEP 2131.01(d) permits the citation of references or extrinsic evidence in an anticipation rejection under 35 U.S.C. 102, including applicant's own specification (e.g. see , *Ex parte Novitski*, 26 USPQ2d 1389 (B.P.A.I, 1993).

The rejection of claims 1-2, 4-10, 13-16 and 19-24 under 35 U.S.C. 112, second paragraph, as being indefinite for the term "a CGRP" is withdrawn in view of applicant's arguments of record.

Applicant's arguments directed to the rejection of claims 14 and 19 under 35 U.S.C. 112, first paragraph for new matter were found persuasive.

Applicant's amendment has overcome the indefinite rejection of claims 14, 18 and 19.

Applicant's arguments directed to the rejection of claims 1, 2, 5, 6, 13, 14 and 20-24 as anticipated by Database WPI, Sec. Week 199546, AN 1995;351860 XP002163755 (1994) were persuasive.

Applicant's amendment has overcome the rejection of claims 17 and 18 as anticipated by Guidobono et al. Brit. J. Pharmacol. (2/97) pages 581-586.

Applicant's amendment has overcome the rejection of claims 17 and 18 under 35 U.S.C. 112, first paragraph.

New (or Modified) Objection (s) and/or Rejection (s)

2. Claims 8, 30 and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kolterman et al., WO 95/07098 (3/95)..

Kolterman et al. disclose the *peripheral* administration of "amylin" or "amylin agonists", especially "amylin agonist analogues" which are preferred (e.g. see pages 29-30) and tri-pro h-amylin which is most preferred (see *tripro 25,28,29 human amylin*, AKA AC-0137: See e.g. page 21 under "Summary of the Invention") for reducing gastric motility and slowing gastric emptying (e.g. See Abstract and PCT claims). In a preferred embodiment, AC-O137 is administered to humans (e.g. by placebo, infusion or by an IV bolus) over a wide range of dosages that are within the scope of the presently claimed invention e.g. "*therapeutic amounts*" as

presently claimed. (E.g. see pages 24-25 and disclosed figures). The mode of peripheral administration (e.g. parenteral, nasal and oral: see e.g. page 42); the amounts administered (e.g. see pages 44-45) and the preferred (e.g. amylin analogues) and most preferred compounds (e.g. tri pro amylin analogues) are within the scope of the presently claimed invention. The reference generic teaching of "parenteral" administration and specifically nasal and oral administration as representative species would immediately envisage (e.g. anticipate) or alternatively render obvious other species of parenteral administration including "pulmonary", "transdermal" or "buccal" due to the limited types of other possible parenteral modalities available which would include "pulmonary", "transdermal" or "buccal" administration. E.g. See e.g. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08.

The actual (e.g. peripheral) administration to humans of compounds (e.g, AC-O137) in dosages within the scope of the presently claimed invention would necessarily anticipate the presently claimed invention drawn to **the prevention** of gastritis/ulcers. Additionally, the reference teaching of the administration of tri pro h-amylin to humans in amounts within the scope of the presently claimed invention directly anticipates and further anticipates (e.g. by immediately envisaging) the selection of the selection of the preferred h-amylin analogues disclosed in the reference due to the small list e.g. 20 or less (e.g. see page 29-30) and page 45 listing the top 7 amylin analogues or alternatively renders obvious the selection of the preferred amylin analogues for use in the disclosed method.

Accordingly, the reference method of reducing gastric motility and slowing gastric emptying (or any of the other reference methods) serves to inherently "prevent" or alternatively would be expected to prevent gastritis (or ulceration) because the *same peptide(s)* is applied in the *same way (e.g. administered in the same way to the same host)* in the *same amount. In re Best*, 195 USPQ 430,433 (CCPA 1977); *Ex parte Novitski*, 26 USPQ2d 1389 (B.P.A.I, 1993). Thus, the reference method which performs the same method steps (e.g. administers the same drug in the same amounts to the same host) would inherently effect the same result (e.g. prevent gastritis or gastric ulceration) regardless of what "induces" the gastritis or ulceration (E.g. alcohol or NSAIDS).

3. Claims 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Guidobono et al. Peptides Vol. 15, No. 4 pages 699-702 (1994).

Guidobono et al. (Peptides) teaches that "peripheral" (e.g. subcutaneous) and "central" administration of "amylin" to a rat (e.g a "subject ") serves to a dose-dependent fall in gastric secretion and acid concentration. E.g. see title, abstract, page 699; and page 701 left column. The reference teaching of "peripheral" administration of "amylin" to reduce gastric secretion would anticipate the use of "amylin" to PREVENT gastritis/gastric ulceration since administering the same agent (e.g. amylin) in the same amounts to the same host (e.g. a subject) in the same manner (e.g. peripherally) MUST have the presently claimed desired preventive effect (anticipating claims 1, 2, 6, 13, 14, and 23 . Similarly, the. reference teaching of "centrally" administering "amylin" to reduce gastric secretion would anticipate the use of "amylin" to PREVENT gastritis/gastric

ulceration since administering the same agent (e.g. amylin) in the same amounts (e.g. "therapeutically effective amount" to the same host (e.g. a subject) in the same manner (e.g. centrally) MUST have the presently claimed desired preventive effect (anticipating claims 17 and 18 which encompasses central administration) .

Discussion

Applicant's argument directed to the above anticipation rejection over the Kolterman et al. or Guidobono reference were considered but deemed nonpersuasive for the following reasons.

Initially, it is noted that the above scope of claims of the above rejections was modified to address the amended and newly added claims.

First, it is noted that applicant's arguments directed toward treatment (e.g. patient must have the condition) is not responsive to the above anticipation rejection.

Applicant argues that the claims have been amended to address patients which are "in need thereof"(e.g. have the claimed disease state). This argument although persuasive for claims 1 and 2 which were amended to recite "in need thereof" is not applicable toward the newly added claims e.g. claims 30 and 31 and claims dependent thereon.

Applicant again is failing to address the crux of the above anticipation rejection e.g. whether the same administration of the same pharmacological agent (e.g. amylin or "agonists" thereof) in the same amounts (e.g. therapeutic amounts) the same "subject" (e.g. **any patient (e.g. the Kolterman patient)** would *necessarily* INHERENTLY achieve the same "preventive" effect (e.g. prevent gastritis or ulceration) as presently claimed. An affirmative answer to this

question is inevitable; especially in the present instance since the reference is clearly targeting the same area of the body (e.g. the stomach) as in the presently claimed invention.

Accordingly, the above rejection is hereby retained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)
December 3, 2001

BENNETT CELSA
PRIMARY EXAMINER